**5. 510(k) Summary** K073522

OCT 10 2008

SAGE Assisted Reproduction Products™

SAGE In-Vitro Fertilization, Inc.
*a CooperSurgical Company*
95 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-4737

| | |
|---|---|
| Submitter's name: | SAGE In-Vitro Fertilization |
| Address: | 95 Corporate Drive<br>Trumbull, CT 09911 |
| Phone: | 203-601-5200 |
| Fax number: | 203-601-4737 |
| Name of contact person: | Grace Holland<br>Regulatory Specialists, Inc<br>3722 Ave. Sausalito<br>Irvine, CA 92606<br>Phone: 949-262-0411<br>Fax: 949-552-2821<br>Email: grace@regulatoryspecialists.com |

Date the summary was prepared: December 11, 2007

| | |
|---|---|
| Name of the device: | Equilibration Solution |
| Trade or proprietary name: | Equilibration Solution |
| Common or usual name: | Equilibration Solution |
| Classification name: | Reproductive media |
| Name of the device: | Vitrification Solution |
| Trade or proprietary name: | Vitrification Solution |
| Common or usual name: | Vitrification Solution |
| Classification name: | Reproductive media |
| Name of the device: | 1.0 M Sucrose Warming Solution |
| Trade or proprietary name: | 1.0 M Sucrose Warming Solution |
| Common or usual name: | 1.0 M Sucrose Warming Solution |
| Classification name: | Reproductive media |
| Name of the device: | 0.5 M Sucrose Warming Solution |
| Trade or proprietary name: | 0.5 M Sucrose Warming Solution |
| Common or usual name: | 0.5 M Sucrose Warming Solution |
| Classification name: | Reproductive media |
| Name of the device: | MOPS Solution |
| Trade or proprietary name: | MOPS Solution |

Common or usual name: MOPS Solution
Classification name: Reproductive media

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

| Device | Ref# | Decided |
|---|---|---|
| Vit Kit – Freeze and Vit Kit - Thaw | K060168 | 04/24/2006 |
| G-FreezeKit Blast | K032154 | 05/07/2004 |
| G-ThawKit Blast | K032155 | 05/07/2004 |

Description of the devices:

There are five (5) solutions that comprise the two kits, Vitrification Kit and Vitrification Warming Kit.

**Vitrification Kit:** Consists of two solutions, Equilibration Solution (ES) and Vitrification Solution (VS) that are intended to be used sequentially, for the preparation for, and cryopreservation of, human blastocysts.

**Equilibration Solution** is used in preparation for freezing and contains dimethyl sulfoxide (DMSO) and ethylene glycol (EG).

**Vitrification Solution** is to be used during cryostorage and contains DMSO and EG and sucrose.

**Vitrification Warming Kit:** The three (3) warming solutions, 1.0 M Sucrose Warming Solution, 0.5 M Sucrose Warming Solution and MOPS Solution, are also intended for sequential use in the warming and recovery of cryopreserved human blastocysts.

Summary of the technological characteristics of both the Sage products and the Irvine Scientific products:

The technological characteristics of the Sage products as compared to the predicate products are similar in the following areas and do not compromise the safety or efficacy of the device.

- Indications For Use
- Formulae
- Performance testing
- Sterility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2008

SAGE In-Vitro Fertilization, Inc.
c/o Ms. Grace Holland
Regulatory Specialist
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K073522
Trade Name: Vitrification Kit & Vitrification Warming Kit
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: September 29, 2008
Received: September 30, 2008

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**4. Indications for Use Statement**

**Indications for Use**

510(k) Number (if known): K 073522

Device Name: Vitrification Kit &
Vitrification Warming Kit

Indications for Use:

**Vitrification Kit:** These products are intended for ultra-rapid freezing and containment of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures. This kit is designed for use with Sage IVF's Vitrification Warming Kit (Ref # ART-8030) for optimal recovery of specimens.

**Vitrification Warming Kit:** These products are intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using Sage IVF's Vitrification Kit (Ref # ART-8025) for Assisted Reproductive Technology (A.R.T.) procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073522

Page 1 of 1